GILEAD

United States House of Representatives
Committee on Government Reform
Testimony of John F. Milligan, PhD
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Mr. Chairman, Congressman Waxman, Committee Members – thank you for the invitation to be here today. I am John Milligan, Executive Vice President and Chief Financial Officer of Gilead Sciences. By way of background, I am a PhD biochemist by training, and I was the project team leader for the development of Tamiflu® by Gilead.

About Gilead Sciences

Gilead is a biopharmaceutical company headquartered in Foster City, California – the district of Congressman Tom Lantos. We also have research facilities in Durham, North Carolina, a manufacturing facility in San Dimas, California, and overseas offices throughout Europe and Australia.

Since Gilead was founded nearly 20 years ago, the company has focused on advancing the care of patients suffering from life-threatening diseases. Over the course of our company's history, Gilead has successfully developed, commercialized and ensured broad access to a portfolio of antiviral medicines in HIV and hepatitis. Today, these important antivirals are improving the quality of life for patients around the globe. Gilead does not achieve this alone, but through a strong commitment to collaboration – working in partnership within our industry, with governments, with health care professionals and with nongovernmental organizations.

Development of Tamiflu (oseltamivir phosphate) – Gilead's Role

As you may know, Gilead is the inventor of Tamiflu, or oseltamivir phosphate. Tamiflu is the first and only antiviral pill available for the treatment and prevention of all common strains of influenza A and B. The compound has been shown to be active in animal models against avian flu, also known as the H5N1 strain of the virus. Tamiflu was discovered by Gilead scientists in 1996, and Gilead conducted all the initial characterization of the compound and developed the manufacturing process for the product.

Also in 1996, Gilead entered into an exclusive agreement with F. Hoffmann-La Roche of Basel, Switzerland, providing for the development and commercialization of Tamiflu worldwide. According to the agreement's terms, Gilead and Roche collaborated on Tamiflu's clinical development, with Gilead successfully managing three out of the four registrational trials leading to FDA approval. Since the U.S. product launch in late 1999, however, Roche has been solely responsible, at its own expense, for product commercialization, including manufacturing, marketing and distribution "in substantially all markets of the world."

While vaccination is the primary weapon in combating influenza, we believe Tamiflu is a key component in addressing the potentially devastating impact of the disease. The role of Tamiflu must be better recognized not just for pandemic planning, but also for seasonal influenza outbreaks. It bears emphasis that Tamiflu is not just effective as a treatment for influenza

patients, but is also an effective influenza prophylactic, meaning it can prevent transmission of the virus. Each year, influenza results in 3 to 5 million cases of severe illness and 250,000 to 500,000 deaths worldwide. In the United States alone, up to 40 million Americans develop the flu, more than 200,000 people are hospitalized and 36,000 people die as a result of the flu and its complications during the average flu season.

Gilead's Partnership with Roche – June 2005 Notice of Termination

Since at least 2001, we believe that our partner, Roche, has neither demonstrated acceptable commitment, nor dedicated adequate resources to Tamiflu. This has led to a lack of awareness of the product and its benefits by health care professionals.

On June 23, Gilead delivered to Roche a notice of termination for material breach of our 1996 Agreement. Gilead's decision to terminate the agreement follows the communication of the company's concerns over a period of several years – concerns communicated repeatedly, without results. We believe our decision to provide notice of termination of the 1996 Agreement is justified by the following material breaches: (1) Roche has failed to use best efforts to commercialize Tamiflu by adequately promoting and marketing the product in a sustained manner in all significant markets; and (2) Roche has failed to use best efforts to commercialize Tamiflu, evidenced by past problems with the manufacturing process that led to recalls and shortages in product supply; and (3) Roche has failed to pay all royalties fairly owed to Gilead.

At its heart, this is a commercial issue between two companies. This is not an action we take lightly. Our actions – and I want to underscore this important point – will not affect current arrangements or planning for the manufacture and supply of Tamiflu. Roche is responsible and will be responsible for ongoing manufacturing until such a time as the termination of our Agreement becomes effective. The Agreement also explicitly provides that, in the event of termination, Roche must continue to supply product for up to two years and must transfer necessary manufacturing technology to Gilead. Consequently, Gilead anticipates a coordinated and orderly process for the transfer of manufacturing, should termination occur. During any period of transition and thereafter, Gilead will honor the supply obligations undertaken by Roche.

I'd like to be especially clear about Gilead's commitment to advancing the care of patients suffering from life-threatening infectious diseases. In the mid and late 1990s Gilead conducted extensive research on oral neuraminidase inhibitors – the class of drug to which Tamiflu belongs. We moved Tamiflu into clinical evaluation because among the compounds we tested, it had the best potential safety and efficacy profile. In accordance with our 1996 contract with Roche, Gilead has continued to conduct extensive research into various compounds that have shown activity against influenza A and B. Many structural classes were identified, however, none of these were thought to have better properties than Tamiflu and none are currently being pursued as viable options for the treatment and prevention of influenza. Any of the compounds would be included in the 1996 agreement between Gilead and Roche, and Gilead would not be free to pursue these on its own.

Manufacturing Expertise

I want to also highlight that Gilead is a leader in the manufacture of antiviral medicines at large scales. Our expertise drawn from experience with HIV therapeutics is highly relevant to the situation surrounding a potential influenza pandemic. Gilead has and is continuing to manage the manufacturing of our HIV products in amounts that well exceed 2004 and anticipated 2005 production volumes for Tamiflu. Comparable to the unpredictability of flu pandemics, the rapidly growing global HIV epidemic has required a carefully structured manufacturing plan for

antiretrovirals, in absence of accurate forecasts estimating the number of patients to be treated for HIV in resource-limited countries in years to come. Further, before issuing the notice of termination, Gilead conducted a thorough internal assessment of our capabilities. We determined we can meet the global pandemic and seasonal needs for Tamiflu and make significant contributions in advancing manufacturing, supply and medical education for this important antiviral medicine.

Need for Ongoing Education

At Gilead, we believe that important lessons can be learned from previous annual influenza seasons – particularly with regards to the administration of Tamiflu. If the effort is made to study the facts and data available to us, and to engage with leaders in global public health, these lessons can and should be applied to enhance responses to both seasonal and pandemic flu events.

For instance, much attention has been drawn to the fact that, in order to be most effective for combating influenza, Tamiflu must be taken within 48 hours of exposure to the virus. It is true that this 48-hour window is absolutely critical to ensure better outcomes for the infected individuals and the existence of this window highlights the importance of advancing education, securing supply and breaking down barriers to rapid access to the product. In order to underscore this crucial point, I have made available to the Members of the Committee a paper published by the *Journal of Antimicrobial Chemotherapy* (accepted on September 24, 2002) on the benefits of early administration of Tamiflu.

Gilead's Commitment to Partnership

Our role, should rights to Tamiflu be returned to Gilead, will be one of planning and partnership. We believe that there is an urgent need for increased education about and access to Tamiflu – not only for pandemic planning purposes, but as importantly for seasonal influenza.

Gilead looks forward to establishing partnerships with the distinguished committee members and government agency representatives here today, and with governments and public health officials around the world. We are prepared to enter into constructive dialogue about the important role of Tamiflu in global public health, which we intend to fully support with appropriate, constructive action. Thank you.